

EPA Jacket 89110-3

PROCESSING REQUEST

Reg # 89110-3

Decision # 550202

Description: CSF Amendment

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: Basic April 4, 2019

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Zebora Johnson

Division: OSCPP/OPP/AD/RMB1

Phone: (703) 308-7080

Date: 9/17/2019



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 27, 2019

Abigail T.D. Wacek
Senior Regulatory Consultant
Technology Sciences Group
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036

Subject: PRIA CSF Amendment – CSF Amendment to add an unregistered source
Product Name: BIONX GA50M
EPA Registration Number: 89110-3
Application Date: April 4, 2019
Decision Number: 550202

Dear Ms. Wacek:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated April 4, 2019
- Alternate CSF 1 dated October 14, 2016
- Alternate CSF 2 dated November 15, 2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080 or via email at johnson.zebora@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be "Zeno Bain", written over a horizontal line.

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

MEMORANDUM

8/8/2019

SUBJECT: Product Chemistry Review for BIONIX GA50M EPA Reg. No.: **89110-3**

FROM: Lynette T. Umez-Eronini *Lynette T. Umez-Eronini*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader *Karen P. Hicks*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Zeno Bain, PM Team 33 / Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: ISOMERIC
INDUSTRIES
Action code: A570
Agency Due Date:
9/9/2019
DP No.: 452292
Submission No.: 1033816
E-Sub No.: 38497
Classification: EP
Process: Integrated
system
Pesticide type:
Antimicrobial

MRID(s):50821200, 50821201

89110-3_D452292_BIONIX GA50M

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
043901	111-30-8	Glutaraldehyde	50.0
		Other Ingredients	50.0
		Total	100.0

I. BACKGROUND

The Registrant, ISOMERIC INDUSTRIES, has submitted a minor formulation amendment for their product: BIONIX GA50M EPA Reg. No. 89110-3.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-1 Application for Pesticide Registration (4/4/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EPA FORM 8570-27 – Formulator’s Exemption Statement	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EPA FORM 8570-34 – Certification with Respect to Citation of Data (4/4/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EPA FORM 8570-35 – Data Matrix (4/4/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cover letter (4/4/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Transmittal document (4/4/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed CSF BASIC, (4/4/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed label,	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Certification for Pilot Fragrance Notification Program	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
REFERENCED: CSF BASIC , (1/15/2017) and LABEL, (9/13/2016)	--	
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use

89110-3_D452292_BIONIX GA50M

Non-integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Active Ingredients(s)	Nominal		Upper limit	Lower limit	
Glutaraldehyde	50.00%		51.50%	48.50%	
	YES		NO	N/A	
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
2. Wider certified limits were requested and rationale was accepted.	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
5. All inert ingredients are approved for non-food use pesticide formulations.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
6. The impurities present >0.1% are identified.	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>	
7. Impurities of toxicological significance have an upper certified limit.	<input type="checkbox"/>		<input type="checkbox"/>	<input checked="" type="checkbox"/>	

b. Product Label:

	Yes	NO	N/A
<i>The formula contains one of the following:</i>			
1. 10% or more of petroleum distillate	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. 1.0% or more of methyl alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Sodium nitrite at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. A toxic list 1 inert at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Arsenic in any form	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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IV. Additional Findings

1. Preliminary analysis and certificate of analysis along with the remaining Group A product chemistry data requirements (MRID 50821201) were provided to support the new active ingredient source product.
2. Basic CSF, dated 4/4/2019 is acceptable and supersedes Basic CSF, dated 1/15/2017.

V. Conclusion

The Product Science Branch of Antimicrobials Division finds Basic CSF, dated 4/4/2019 to be acceptable and to supersede all previous Basic CSFs with the same formulation.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 07, 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

TECHNOLOGY SCIENCES GROUP INC.
ISOMERIC INDUSTRIES
1150 18TH STREET, NW - SUITE 1000
WASHINGTON, DC 20036

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 17-APR-19. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

**VOLUME 1 OF 2 OF SUBMISSION
TRANSMITTAL DOCUMENT****NAME AND ADDRESS OF SUBMITTER:**

Isomeric Industries
3400 Research Forest Drive, Suite B4
The Woodlands, TX 77381

REGULATORY ACTION:

A570 application to add unregistered source to *BIONIX GA50M*, 89110-3.

TRANSMITTAL DATE:

April 4, 2019

LIST OF SUBMITTED STUDIES:

<u>MRID Number</u>	<u>Volume Number</u>	<u>EPA Study Title</u>	<u>Guideline Number</u>
50821200	1 of 3	Administrative Materials	---
50821201	2 of 3	Product Chemistry of Bionix GA50M - Group A	830.1600 – 830.1700

COMPANY NAME: Isomeric Industries

COMPANY OFFICIAL:


Abigail T.D. Wacek, Senior Regulatory Consultant

COMPANY CONTACT:

Technology Sciences Group
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Phone: 202-828-8992
Email: abigail.wacek@tsgconsulting.com



a science group company

Technology Sciences Group Inc.
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Direct: (202) 828-8992
Fax: (202) 872-0745
E-Mail: abigail.wacek@tsgconsulting.com
Abigail T. D. Wacek
Regulatory Consultant

April 4, 2019

Zeno Bain, PM 33
Antimicrobials Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Submitted via CDX

Re: A570 – Amendment Requiring Data Review
Company Name: Isomeric Industries
Product Name: *BIONIX GA50M*
EPA Reg. No.: 89110-3

Dear Mr. Bain,

Technology Sciences Group, Inc., on behalf of Isomeric Industries, hereby submits this amendment to add an unregistered source to the *BIONIX GA50M* registration. Please find the following enclosed to support this application:

1. EPA Form 8570-1, Application for Registration;
2. EPA Form 8570-4, Confidential Statement of Formula, Basic;
3. EPA Form 8570-34, Certification with Respect to Citation of Data;
4. EPA Form 8570-35, Data Matrix, confidential and releasable versions;
5. Transmittal document and product chemistry data volume 2, MRID 50821201;
6. PRIA category A570 pre-payment receipt, Pay.gov Tracking ID: 26GEHB5A, Agency Tracking ID: 75714085315
7. Small Business Fee waiver certification letter.

Please do not hesitate to contact me with any questions at 202-828-8992 or via e-mail: Abigail.wacek@tsgconsulting.com.

Sincerely,

Abigail T.D. Wacek
Senior Regulatory Consultant

From: Ron Starkey
To: Wacek, Abigail
Cc: Chris Harken
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Wednesday, April 3, 2019 7:00:02 PM

Abigail,

Here is the payment email again.

Hope all is well,



Ron Starkey
General Manager - Biocides
3400 Research Forest Drive, Suite B-4
The Woodlands, Texas 77381
ron.starkey@isomericindustries.com
(985) 520-2370 - mobile

From: notification@pay.gov <notification@pay.gov>
Sent: Friday, March 29, 2019 10:01 AM
To: Ron Starkey <ron.starkey@isomericindustries.com>
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

 An official email of the United States government

Pay.gov logo



Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 26GEHB5A
Agency Tracking ID: 75714085315
Transaction Type: Sale
Transaction Date: 03/29/2019 11:01:21 AM EDT

From: [Ron Starkey](#)
To: [Wacek, Abigail](#)
Cc: [Chris Harken](#)
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Wednesday, April 3, 2019 7:00:02 PM

Abigail,


Here is the payment email again.

Hope all is well,



Ron Starkey
General Manager - Biocides
3400 Research Forest Drive, Suite B-4
The Woodlands, Texas 77381
ron.starkey@isomericindustries.com
(985) 520-2370 - mobile

From: notification@pay.gov <notification@pay.gov>
Sent: Friday, March 29, 2019 10:01 AM
To: Ron Starkey <ron.starkey@isomericindustries.com>
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

 An official email of the United States government

Pay.gov logo




Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 26GEHB5A
Agency Tracking ID: 75714085315
Transaction Type: Sale
Transaction Date: 03/29/2019 11:01:21 AM EDT

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number 89110-3		2. EPA Product Manager Zeno Bain	
4. Company/Product (Name) Isomeric Industries / BIONIX GA50M		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name And Address Of Applicant (Include ZIP Code) Isomeric Industries 361 17th Street NW #1224 Atlanta, GA 30363		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address			
Section II			
<input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Notification – Explain below. <input type="checkbox"/> Other – Explain Below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) A570 PRIA amendment requiring data review to add an unregistered source. A PRIA pre-payment has been made for this action and receipt included in this application (Pay.gov Tracking ID: 26GEHB5A Agency Tracking ID: 75714085315). Please confirm receipt and forward all communication to <u>Abigail Wacek, Technology Sciences Group, 1150 18th Street, NW, Suite 1000, Washington, D.C. 20036 or Abigail.wacek@tsqconsulting.com.</u>			
Section III			
1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container 5 gal pail; 15, 30, 55 gal drum; 275, 330 gal tote bin, bulk tanker	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
<input type="checkbox"/> Other _____ Self adhesive			
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Abigail Wacek, Technology Sciences Group		Title Senior Regulatory Consultant Telephone No. (Include Area Code) 202-828-8992	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received (Stamped)
2. Signature 		3. Title Senior Regulatory Consultant	
4. Typed Name Abigail T.D. Wacek		5. Date April 4, 2019	

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4/17/19

Experts In-Processing Signature: [Signature] Date 4/24/19 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>89110-3</u>		EPA Receipt Date: <u>4/17/19</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)					X
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

- o Documentation: Pass
 - Required forms are complete
- o Inerts: Pass
 - Inerts approved for Non-Food Use
- o 11/3: Pass
 - MRID: 508212
- o Overall Status: Pass

SE 5/7/2019

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 5, 2018

Abigail T.D. Wacek
Regulatory Consultant
Isometric Industries Inc.
361 17th Street NW #1224
Atlanta, GA 30363

Subject: Notification per PRN 98-10 – Adding Alternate Brand Name
Product Name: BIONIX GA50M
EPA Registration Number: 89110-3
Application Date: 09/07/2018
Decision Number: 544211

Dear Ms. Wacek:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name BIONIX GA50HM has been added to the product record.

If you have any questions, you may contact Jake Farley at (703) 347-0123 or via email at Farley.Jake@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Zeno Bain", is written over a horizontal line.

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Farley, Jake

From: Farley, Jake
Sent: Friday, October 5, 2018 1:24 PM
To: 'Wacek, Abigail'
Cc: Bain, Zeno; OPP AD Ombudsman
Subject: EPA Completed Action (89110-3)
Attachments: 89110-3-20181005.pdf

Good Afternoon,

Please see the attached letter.

Best,

Jake Farley

Jake Farley | Risk Manager | Regulatory Management Branch 1 | Antimicrobials Division
U.S. Environmental Protection Agency, Office of Pesticides Programs
(703)347-0123 | Farley.Jake@epa.gov



a science group company

Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000

Washington, D.C. 20036

Direct: (202) 828-8992

Fax: (202) 872-0745

E-Mail: awacek@tsgusa.com

Abigail T. D. Wacek

Regulatory Consultant

September 7, 2018

Zeno Bain, PM 33
Antimicrobials Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Submitted via CDX

Re: Notification to Add Alternate Brand Name per PR Notice 98-10
Company Name: Isomeric Industries
Product Name: *BIONIX GA50M*
EPA Reg. No.: 89110-3

Dear Zeno,

Technology Sciences Group, Inc., on behalf of Isomeric Industries, hereby submits this notification to add an alternate brand name to the aforementioned product registration. With this notification, Isomeric adds the following alternate brand name:

- BIONIX GA50HM

Please find the following enclosed to support this application:

1. EPA Form 8570-1, Application for Registration.

Please do not hesitate to contact me with any questions at 202-828-8992 or via e-mail: awacek@tsgusa.com.

Sincerely,

Abigail T.D. Wacek
Regulatory Consultant

TSG Consulting

1150 18th Street, NW

Suite 1000, Washington, DC 20036

T +1 (202) 828-8990

E info@tsgconsulting.com

www.tsgconsulting.com

CONFIDENTIAL

		United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I					
1. Company/Product Number 89110-3		2. EPA Product Manager Zeno Bain		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Isomeric Industries Inc. / Bionix GA50M		PM# 33			
5. Name And Address Of Applicant (Include ZIP Code) Isomeric Industries Inc. 361 17th Street NW #1224 Atlanta, GA 30363		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
<input type="checkbox"/> Check if this is a new address					
Section II					
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Notification – Explain below. <input type="checkbox"/> Other – Explain Below.					
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification to add Alternate Brand Name. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please confirm receipt and forward all communication to Abigail Wacek, Technology Sciences Group, 1150 18th Street, NW, Suite 1000, Washington, D.C. 20036 or awacek@tsqusa.com.					
Section III					
1. Material This Product Will Be Packaged In:					
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Packaging wgt. No. per Container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			
Section IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Abigail Wacek, Technology Sciences Group		Title Regulatory Consultant		Telephone No. (Include Area Code) 202-828-8992	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) <div style="border: 1px solid black; padding: 5px; width: fit-content; float: right;"> SEP 7 2018 </div>
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Abigail T.D. Wacek		5. Date September 7, 2018			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 16, 2018

Abigail Wacek
Regulatory Consultant
Isomeric Industries
361 17th Street NW #1224
Atlanta, GA 30363

Subject: PRIA CSF Amendment – Revised Basic CSF and Alternate CSF 2
Product Name: Bionix GA50M
EPA Registration Number: 89110-3
Application Date: August 8, 2017
Decision Number: 532735

Dear Ms. Wacek:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/15/2017
- Alternate CSF 1 dated 10/14/2016
- Alternate CSF 2 dated 11/15/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be "Zeno Bain", written over a horizontal line.

Zeno Bain, Acting Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Northern, Terria

From: Abigail Wacek <AWacek@tsgusa.com>
Sent: Thursday, January 04, 2018 2:51 PM
To: ODell, Lindsay; Northern, Terria
Cc: Bain, Zeno
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action
Attachments: RE: Product Chemistry Review 89110-3_DP442578_BionixGA50M.pdf

Lindsay,

I submitted a revise copy of the guideline 830.1620 to Terria on December 27, please see attached. I believe that this should address the question in 4.4. Can you please confirm that you received this document? Please let me know if you received this and it does not satisfy the question and we will do our best to get you what you need.

Thank you,

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
www.tsgusa.com

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A Science Group Company

From: ODell, Lindsay [mailto:odell.lindsay@epa.gov]
Sent: Wednesday, January 03, 2018 13:27
To: Abigail Wacek; Northern, Terria
Cc: Bain, Zeno
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Hi Abigail,

I've looked over the responses provided to the agency regarding the product chemistry review for 89110-3. Your response to comment 4.4 was that clarification is requested from the supplier in [REDACTED] and made available to the agency by COB on 12/27.

I wanted to follow-up with you to see if you have received any additional information from the supplier.

Thanks,

Lindsay O'Dell

Environmental Protection Specialist
Antimicrobials Division
EPA
703.347.0392

From: Abigail Wacek [mailto:AWacek@tsgusa.com]
Sent: Friday, December 22, 2017 12:07 PM
To: Northern, Terria <Northern.Terria@epa.gov>; ODell, Lindsay <odell.lindsay@epa.gov>
Cc: Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Terria,

I realized I had the wrong date on the cover letter. Please disregard my previous email and see the revised submission attached.

Thank you.

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
www.tsgusa.com

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I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

From: Abigail Wacek
Sent: Friday, December 22, 2017 12:00
To: 'Northern, Terria'; ODell, Lindsay
Cc: Bain, Zeno
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Terria,

I will submit the information for the -RN to a separate email. Please see our responses to the -3 attached.

I also realized that we are missing page 6 of the product chemistry review. Can you please re-send this document?

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
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A Science Group Company

From: Northern, Terria [<mailto:Northern.Terria@epa.gov>]
Sent: Thursday, December 21, 2017 11:00
To: Abigail Wacek; ODell, Lindsay
Cc: Bain, Zeno
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Hello Abby – just to recap our phone conversation the same approach to resolve the issues identified for 89110-3, will be used for 89110-RN. Submission date December 27th.

Thanks!

Terria Northern
Registration Risk Manager
Environmental Protection Agency
1200 Penn. Ave., NW (7510P)
Washington, DC 20460
#703-347-0265

Street address: 2777 Crystal Drive
1 Potomac Yard South
Arlington, VA

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Wednesday, December 20, 2017 11:19 AM
To: ODell, Lindsay <odell.lindsay@epa.gov>; Northern, Terria <Northern.Terria@epa.gov>
Cc: Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Lindsay, Terria,

Thank you for your time this morning. Per our discussion I will work to get clarity on [REDACTED]
[REDACTED]

Manufacturing process information may be entitled to confidential treatment

██████████ in the formulation. As we discussed we will have this information to you no later than COB December 27 in order allow you time to review the information to meet the PRIA deadline.

Thank you,

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
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I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

From: ODell, Lindsay [<mailto:odell.lindsay@epa.gov>]
Sent: Tuesday, December 19, 2017 08:51
To: Abigail Wacek; Northern, Terria
Cc: Bain, Zeno
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Abigail,

Tomorrow at 10am is fine with me. Thanks!

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Tuesday, December 19, 2017 8:45 AM
To: ODell, Lindsay <odell.lindsay@epa.gov>; Northern, Terria <Northern.Terria@epa.gov>
Cc: Bain, Zeno <Bain.Zeno@epa.gov>
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Lindsay,

Thank you for your email. I am available any time before 11:30 tomorrow. How about 10? I would also like to invite our chemist to be on the line, if that is ok.

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992

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I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

-----Original Message-----

From: ODell, Lindsay [<mailto:odell.lindsay@epa.gov>]

Sent: Tuesday, December 19, 2017 08:37

To: Northern, Terria; Abigail Wacek

Cc: Bain, Zeno

Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Hi Abigail,

Would you be available tomorrow sometime between the hours of 8am-12pm to have a brief call to further discuss the product chemistry issues? My number is 703-347-0392, please let me know a time convenient for you.

Thank you,
Lindsay

-----Original Message-----

From: Northern, Terria

Sent: Friday, December 15, 2017 10:13 AM

To: Abigail Wacek <AWacek@tsgusa.com>

Cc: Bain, Zeno <Bain.Zeno@epa.gov>; ODell, Lindsay <odell.lindsay@epa.gov>

Subject: Registrant Response Requested EPA Request 89110-3 PRIA Action

Hello Abby - I am copying the product chemistry reviewer for a response.

Thanks!

From: Abigail Wacek [AWacek@tsgusa.com]

Sent: Friday, December 15, 2017 9:46 AM

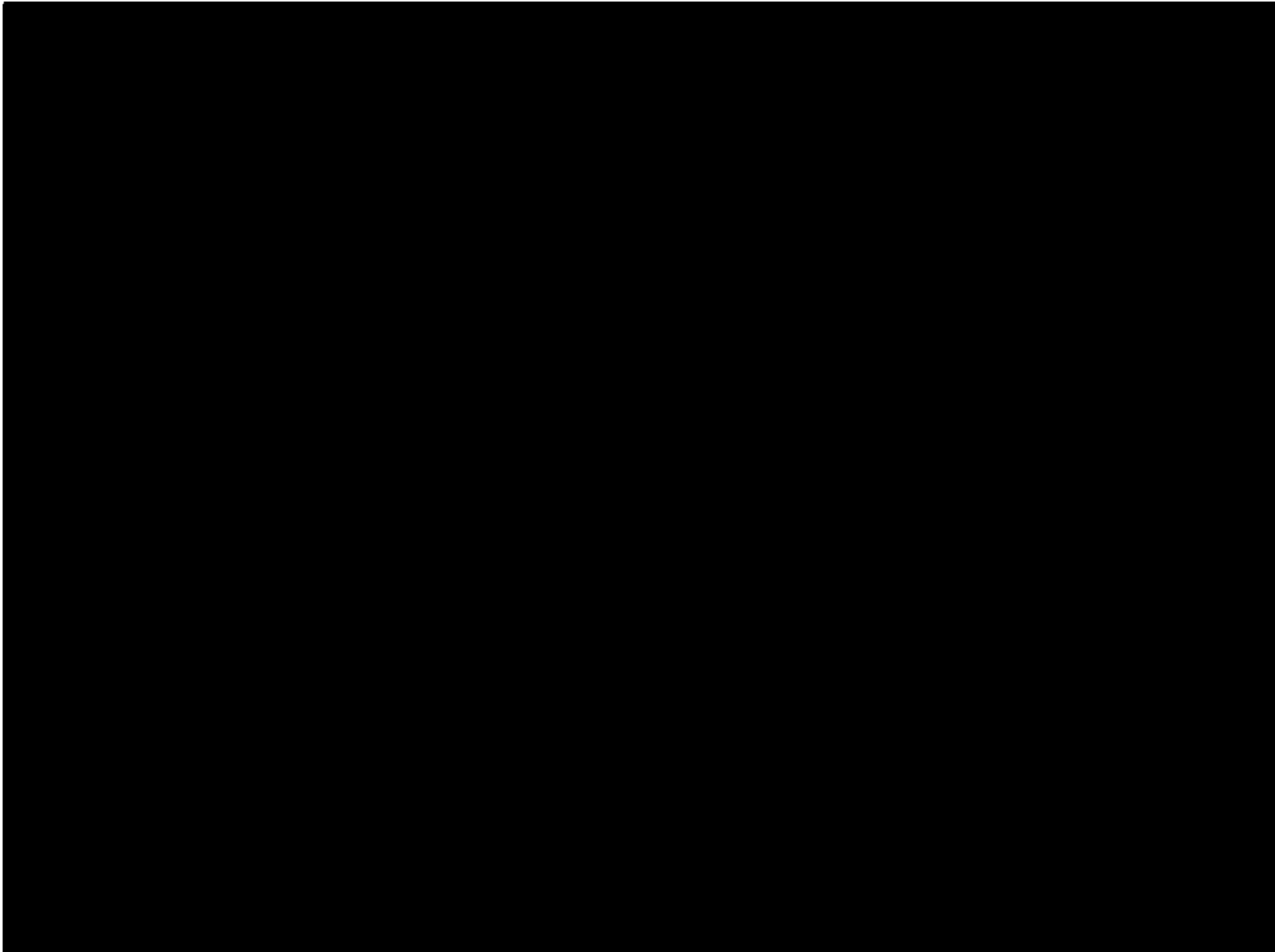
To: Northern, Terria

Subject: RE: EPA Request 89110-3 PRIA Action

Terria,



Manufacturing process information may be entitled to confidential treatment



Type of Process:

Batch

Type of Process:

Batch

Product ingredient source information may be entitled to confidential treatment

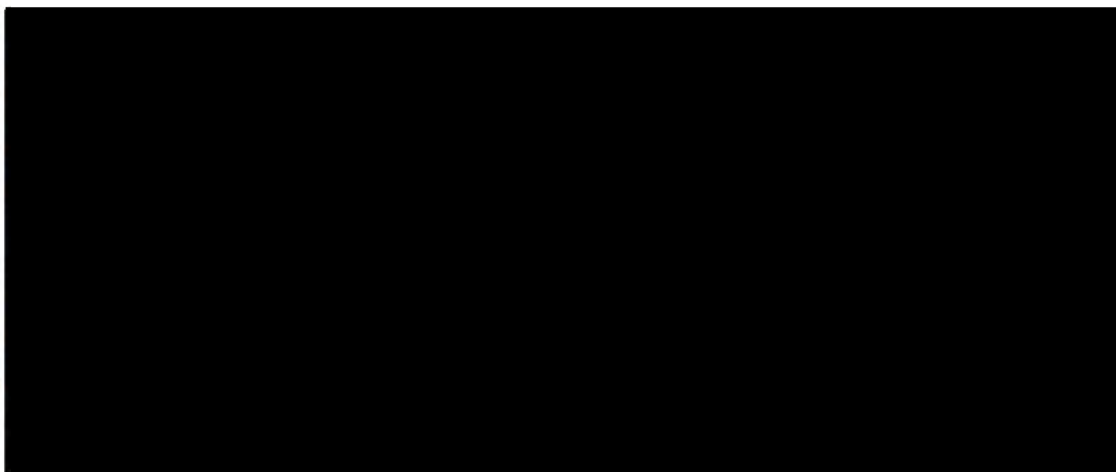
Type of Process:

Batch

Type of Process:

Continuous

Starting manufacturing process of Glutaraldehyde - Stage #



Thank you!

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
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Follow us on: LinkedIn<<https://www.linkedin.com/company/731258/>> | Twitter<<https://twitter.com/TSGUSA>>
|

I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

From: Abigail Wacek
Sent: Thursday, December 14, 2017 12:43
To: 'Northern, Terria'
Cc: Bain, Zeno; ODell, Lindsay
Subject: RE: EPA Request 89110-3 PRIA Action

Terria,



Will addition of these statements fully address the reviewer's comment or is any additional information required?

Thank you,

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
www.tsgusa.com <<http://www.tsgusa.com/>>

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|

I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

From: Northern, Terria [<mailto:Northern.Terria@epa.gov>]
Sent: Thursday, December 14, 2017 11:03
To: Abigail Wacek
Cc: Bain, Zeno; ODell, Lindsay
Subject: EPA Request 89110-3 PRIA Action

Hello Abby - please review the attached product chemistry report for 89110-3. Unfortunately the following guidelines were not met 830.1620 and 830.1670. A response is due back to the Agency by 12/21/17.

Thanks!

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

MEMORANDUM

1/4/2018

SUBJECT: Product Chemistry Review for **BIONIX GA50M** EPA Reg. No.: **89110-3**

FROM: Lindsay O'Dell

Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

L O'Dell

THRU: Karen P. Hicks, Team Leader

Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

KPH

TO: Zeno Bain, PM Team 33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Isomeric
Industries

Action code: A570

Agency Due Date:
1/19/2018

DP No.: 442578

Submission No.: 1008303

E-Sub No.: 22110

Classification: MUP

Process: Integrated
system

Pesticide type:
Microbiocide

MRID(s):50011201, S0011202

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
043901	111-30-8	Glutaraldehyde	50.0%
		Other Ingredients	50.0%
		Total	100%

I. BACKGROUND

The Registrant, Isomeric Industries, has submitted an amendment requiring data review for their product: BIONIX GA50M EPA Reg. No. 89110-3. The purpose of this amendment is to add an unregistered source of active ingredient. The is a manufacturing use product intended for the formulation of industrial bactericides and preservations.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-27 – Formulator’s Exemption Statement	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EPA FORM 8570-35 – Data Matrix (8/8/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cover letter (11/8/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Transmittal document	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed CSF BASIC, (11/15/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed CSF ALTERNATE 2, (11/15/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Integrated	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
Active Ingredients(s)	Nominal		Upper limit	Lower limit	
Glutaraldehyde	50.0%		51.50%	48.5%	
	YES		NO	N/A	
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
2. Wider certified limits were requested and rationale was accepted.	<input type="checkbox"/>		<input checked="" type="checkbox"/>		
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	<input checked="" type="checkbox"/>		<input type="checkbox"/>		

4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. All inert ingredients are approved for non-food use pesticide formulations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The impurities present >0.1% are identified.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Impurities of toxicological significance have an upper certified limit.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Product Label:

	Yes	NO	N/A
<i>The formula contains one of the following:</i>			
1. 10% or more of petroleum distillate	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. 1.0% or more of methyl alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Sodium nitrite at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. A toxic list 1 inert at any level	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Arsenic in any form	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

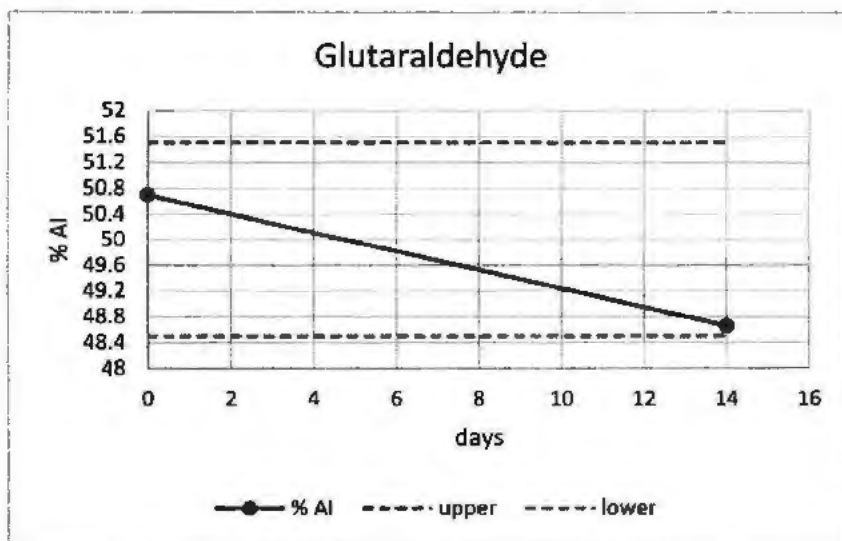
IV. Additional Findings

4.1. – 4.4. See confidential attachment.

4.5. Storage stability results

Study Conditions	
Date(s): April 27, 2017- May 12, 2017	Duration: 14 days
Temperature: 54°C ±2°C	Relative humidity: N/A
GLP Compliance Statement: acceptable	Quality Assurance Statement: acceptable
Commercial package: HDPE bottle	

INTERVAL	average % Active ingredient
Initial	50.70%
Day 14	48.65%



V. Conclusion

The Series 830 Group A and B Guidelines have been met. The Basic CSF (11/15/2017) is acceptable. The Alternate CSF #2 (11/15/2017) is acceptable.

VI. Table A:
Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50011201
830.1600	Description of materials	Acceptable	50011201
830.1620	Description of production process	Acceptable	50011201
830.1650	Description of formulation process	Not required	N/A
830.1670	Discussion of formation of impurities	Acceptable	50011201
830.1700	Preliminary analysis	Acceptable	50011201
830.1750	Certified limits	Acceptable	50011201
830.1800	Enforcement analytical method	Acceptable	50011201
830.1900	Submittal of samples	Acceptable	50011201

VII. Table B: Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Colorless to yellow	Acceptable	50011202
830.6303	Physical state	liquid	Acceptable	50011202
830.6304	Odor	pungent odor	Acceptable	50011202
830.6313	Stability to normal & elevated temperatures, metals & metal ions	Not required for MUP	Not applicable	N/A
830.6314	Oxidation/Reduction	This product is a strong reducing agent, should not be mixed with oxidizing agents.	Acceptable	50011202
830.6315	Flammability	>100°C	Acceptable	50011202
830.6316	Explosibility	Product does not contain explosive ingredients	Waived	50011202
830.6317	Storage stability	The nominal concentration of active ingredient was maintained within EPA standard certified limits; see additional finding 4.4.	Acceptable	50011202
830.6319	Miscibility	Product not mixed with organic solvents	Waived	50011202
830.6320	Corrosion characteristics	HDPE storage container had a dimpled appearance at the end of the test period.	Acceptable	50011202
830.6321	Dielectric breakdown voltage	Not required for MUP	Not applicable	N/A
830.7000	pH	3.55 in 1% w/w; range 3-4	Acceptable	50011202
830.7050	UV/Visible absorption	Not required for MUP	Not applicable	N/A
830.7100	Viscosity	18.9 cSt at 20°C	Acceptable	50011202
830.7200	Melting point	Not required for MUP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP	Not applicable	N/A
830.7300	Density/relative	1.12-1.14 g/mL (9.35-9.51 lbs/gal)	Acceptable	50011202
830.7370	Dissociation constants in water	Not required for MUP	Not applicable	N/A
830.7520	Particle size	Not required for MUP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP	Not applicable	N/A

830.7840/ 7860	Water solubility	Not required for MUP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP	Not applicable	N/A

Page 40*Manufacturing process information may be entitled to confidential treatment**Product ingredient source information may be entitled to confidential treatment*

Northern, Terria

From: Abigail Wacek <AWacek@tsgusa.com>
Sent: Wednesday, December 20, 2017 11:19 AM
To: ODell, Lindsay; Northern, Terria
Cc: Bain, Zeno
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Categories: Red Category

Lindsay, Terria,

Thank you for your time this morning. Per our discussion I will work to get clarity on [REDACTED]
[REDACTED] in the formulation. As we discussed we will have this information to you no later than COB December 27 in order allow you time to review the information to meet the PRIA deadline.

Thank you,

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
www.tsgusa.com

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I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

From: ODell, Lindsay [mailto:odell.lindsay@epa.gov]
Sent: Tuesday, December 19, 2017 08:51
To: Abigail Wacek; Northern, Terria
Cc: Bain, Zeno
Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Abigail,

Tomorrow at 10am is fine with me. Thanks!

From: Abigail Wacek [mailto:AWacek@tsgusa.com]
Sent: Tuesday, December 19, 2017 8:45 AM
To: ODell, Lindsay <odell.lindsay@epa.gov>; Northern, Terria <Northern.Terria@epa.gov>

Cc: Bain, Zeno <Bain.Zeno@epa.gov>

Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Lindsay,

Thank you for your email. I am available any time before 11:30 tomorrow. How about 10? I would also like to invite our chemist to be on the line, if that is ok.

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

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I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

-----Original Message-----

From: ODell, Lindsay [<mailto:odell.lindsay@epa.gov>]

Sent: Tuesday, December 19, 2017 08:37

To: Northern, Terria; Abigail Wacek

Cc: Bain, Zeno

Subject: RE: Registrant Response Requested EPA Request 89110-3 PRIA Action

Hi Abigail,

Would you be available tomorrow sometime between the hours of 8am-12pm to have a brief call to further discuss the product chemistry issues? My number is 703-347-0392, please let me know a time convenient for you.

Thank you,
Lindsay

-----Original Message-----

From: Northern, Terria

Sent: Friday, December 15, 2017 10:13 AM

To: Abigail Wacek <AWacek@tsgusa.com>

Cc: Bain, Zeno <Bain.Zeno@epa.gov>; ODell, Lindsay <odell.lindsay@epa.gov>

Subject: Registrant Response Requested EPA Request 89110-3 PRIA Action

Hello Abby - I am copying the product chemistry reviewer for a response.

Thanks!

From: Abigail Wacek [AWacek@tsgusa.com]
Sent: Friday, December 15, 2017 9:46 AM
To: Northern, Terria
Subject: RE: EPA Request 89110-3 PRIA Action

Terria,



Product ingredient source information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment



Type of Process:

Batch

Type of Process:

Batch

Type of Process:

Batch

Type of Process:

Continuous

Starting manufacturing process of Glutaraldehyde - Stage #



Thank you!

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036

United States of America

Tel: (202) 828-8992

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I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

From: Abigail Wacek

Sent: Thursday, December 14, 2017 12:43

To: 'Northern, Terria'

Cc: Bain, Zeno; ODell, Lindsay

Subject: RE: EPA Request 89110-3 PRIA Action

Terria,

Will addition of these statements fully address the reviewer's comment or is any additional information required?

Thank you,

Abigail T.D. Wacek

Regulatory Consultant

Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000

Washington D.C., 20036

United States of America

Tel: (202) 828-8992

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I will be out of the office the afternoon of Friday, December 22 through Monday, January 1.

A Science Group Company

From: Northern, Terria [<mailto:Northern.Terria@epa.gov>]

Sent: Thursday, December 14, 2017 11:03
To: Abigail Wacek
Cc: Bain, Zeno; ODell, Lindsay
Subject: EPA Request 89110-3 PRIA Action

Hello Abby - please review the attached product chemistry report for 89110-3. Unfortunately the following guidelines were not met 830.1620 and 830.1670. A response is due back to the Agency by 12/21/17.

Thanks!

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

MEMORANDUM

12/14/2017

SUBJECT: Product Chemistry Review for **BIONIX GA50M** EPA Reg. No.: **89110-3**

FROM: Lindsay O'Dell

Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

L O'Dell

THRU: Karen P. Hicks, Team Leader

Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

KPH

TO: Zeno Bain, PM Team 33 / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Isomeric
Industries

Action code: A570

Agency Due Date:
1/19/2018

DP No.: 442578

Submission No.: 1008303

E-Sub No.: 22110

Classification: MUP

Process: Integrated
system

Pesticide type:
Microbiocide

MRID(s):50011201, 50011202

Formulation from label			
PC code(s)	CA5 #(s)	Active Ingredient(s)	% weight
043901	111-30-8	Glutaraldehyde	50.0%
		Other Ingredients	50.0%
		Total	100%

I. BACKGROUND

The Registrant, Isomeric Industries, has submitted an amendment requiring data review for their product: BIONIX GA50M EPA Reg. No. 89110-3. The purpose of this amendment is to add an unregistered source of active ingredient. The is a manufacturing use product intended for the formulation of industrial bactericides and preservations.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-27 – Formulator's Exemption Statement	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EPA FORM 8570-35 – Data Matrix (8/8/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cover letter (11/8/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Transmittal document	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed CSF BASIC, (11/15/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed CSF ALTERNATE 2, (11/15/2017)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Integrated	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
Active Ingredients(s)			Nominal	Upper limit	Lower limit
Glutaraldehyde			50.0%	51.50%	48.5%
			YES	NO	N/A
1. The certified limits of all ingredients are within 40 CFR standard certified limits.			<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Wider certified limits were requested and rationale was accepted.			<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3. The nominal concentration(s) of the active ingredient is in agreement with the label.			<input checked="" type="checkbox"/>	<input type="checkbox"/>	

4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. All inert ingredients are approved for non-food use pesticide formulations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The impurities present >0.1% are identified.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Impurities of toxicological significance have an upper certified limit.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Product Label:

	Yes	NO	N/A
<i>The formula contains one of the following:</i>			
1. 10% or more of petroleum distillate	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. 1.0% or more of methyl alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Sodium nitrite at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. A toxic list 1 inert at any level	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Arsenic in any form	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

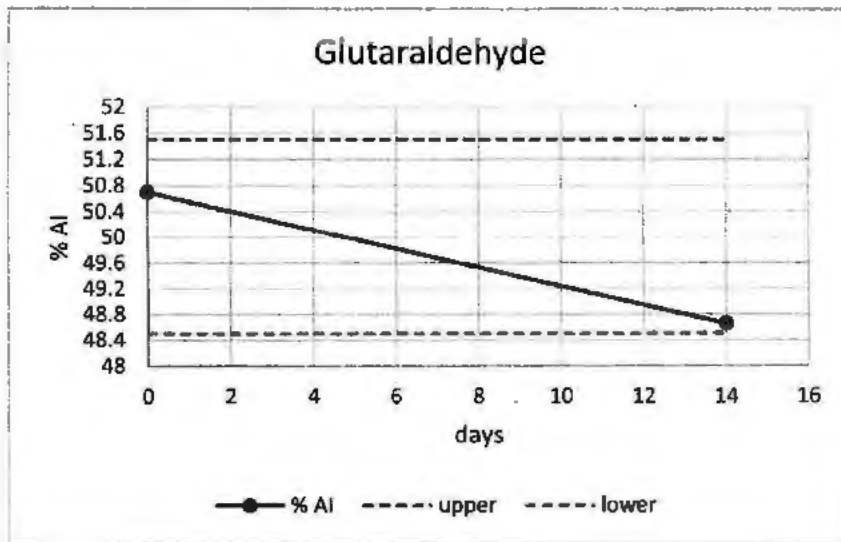
IV. Additional Findings

4.1. – 4.4. See confidential attachment.

4.5. Storage stability results

Study Conditions	
Date(s): April 27, 2017- May 12, 2017	Duration: 14 days
Temperature: 54°C ±2°C	Relative humidity: N/A
GLP Compliance Statement: acceptable	Quality Assurance Statement: acceptable
Commercial package: HDPE bottle	

INTERVAL	average % Active ingredient
Initial	50.70%
Day 14	48.65%



V. Conclusion

The Series 830 Group A guidelines 830.1620 and 830.1670 require upgrading. Consequently, the Basic CSF (11/15/2017) is not accepted. The Series 830 Group B guidelines have been met. The alternate CSF #2 (11/15/2017) is acceptable.

VI. Table A:**Series 830 guidelines – Group A**

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50011201
830.1600	Description of materials	Acceptable	50011201
830.1620	Description of production process	Requires upgrading; see additional finding 4.4	50011201
830.1650	Description of formulation process	Not required	N/A
830.1670	Discussion of formation of impurities	Requires upgrading; see additional finding 4.2	50011201
830.1700	Preliminary analysis	Acceptable	50011201
830.1750	Certified limits	Acceptable	50011201
830.1800	Enforcement analytical method	Acceptable	50011201
830.1900	Submittal of samples	Acceptable	50011201

VII. Table B: Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Colorless to yellow	Acceptable	50011202
830.6303	Physical state	liquid	Acceptable	50011202
830.6304	Odor	pungent odor	Acceptable	50011202
830.6313	Stability to normal & elevated temperatures, metals & metal ions	Not required for MUP	Not applicable	N/A
830.6314	Oxidation/Reduction	This product is a strong reducing agent, should not be mixed with oxidizing agents.	Acceptable	50011202
830.6315	Flammability	>100°C	Acceptable	50011202
830.6316	Explodability	Product does not contain explosive ingredients	Waived	50011202
830.6317	Storage stability	The nominal concentration of active ingredient was maintained within EPA standard certified limits; see additional finding 4.4.	Acceptable	50011202
830.6319	Miscibility	Product not mixed with organic solvents	Waived	50011202
830.6320	Corrosion characteristics	HDPE storage container had a dimpled appearance at the end of the test period.	Acceptable	50011202
830.6321	Dielectric breakdown voltage	Not required for MUP	Not applicable	N/A
830.7000	pH	3.55 in 1% w/w; range 3-4	Acceptable	50011202
830.7050	UV/Visible absorption	Not required for MUP	Not applicable	N/A
830.7100	Viscosity	18.9 cSt at 20°C	Acceptable	50011202
830.7200	Melting point	Not required for MUP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP	Not applicable	N/A
830.7300	Density/relative	1.12-1.14 g/mL (9.35-9.51 lbs/gal)	Acceptable	50011202
830.7370	Dissociation constants in water	Not required for MUP	Not applicable	N/A
830.7520	Particle size	Not required for MUP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP	Not applicable	N/A

830.7840/ 7860	Water solubility	Not required for MUP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP	Not applicable	N/A

Page 54*Manufacturing process information may be entitled to confidential treatment**Product ingredient source information may be entitled to confidential treatment*

Northern, Terria

From: Abigail Wacek <AWacek@tsgusa.com>
Sent: Wednesday, November 15, 2017 10:02 AM
To: Northern, Terria; Bain, Zeno
Subject: RE: EPA Completed Action 89110-3
Attachments: 8570-4 CSF_Alt 2 v 3_BIONIX GA50M.pdf; 8570-4 CSF_Basic_BIONIX GA50M.pdf

Categories: Red Category

Terria,

I am so sorry but I realized another typo on the basic attachment. Please disregard my previous emails and see the clean revised CSFs attached.

Sorry for spamming you.

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992
www.tsgusa.com

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A Science Group Company

I will be out of the office the afternoon of November 17 through Friday, November 24.

From: Abigail Wacek
Sent: Wednesday, November 15, 2017 09:59
To: 'Northern, Terria'; 'Bain, Zeno'
Subject: RE: EPA Completed Action 89110-3

Terria,

Please see the updated alternate #2 CSF attached. I accidentally forgot to update box 4.

Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America

Tel: (202) 828-8992

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A Science Group Company

I will be out of the office the afternoon of November 17 through Friday, November 24.

From: Abigail Wacek

Sent: Wednesday, November 15, 2017 09:57

To: 'Northern, Terria'; Bain, Zeno

Subject: RE: EPA Completed Action 89110-3

Terria,

Please see the updated basic and alternate formulation #2 attached. To address the second deficiency, OCSPP Guideline Number 830.6321, Dielectric Breakdown Voltage Study was not addressed because as per 830.1000, 830.6321 is not required to be addressed for Manufacturing Use Products.

I believe that this should address the deficiencies in the November 3 letter. Please let me know if I can provide any additional information.

Thank you,

Abby

Abigail T.D. Wacek

Regulatory Consultant

Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000

Washington D.C., 20036

United States of America

Tel: (202) 828-8992

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A Science Group Company

I will be out of the office the afternoon of November 17 through Friday, November 24.

From: Northern, Terria [<mailto:Northern.Terria@epa.gov>]

Sent: Tuesday, November 14, 2017 08:44

To: Abigail Wacek; Bain, Zeno

Subject: RE: EPA Completed Action 89110-3

Hello Abby –

Correct per the technical screen letter. We are requesting Alt CSF#2 become the Basic CSF, and the current Basic CSF become Alt CSF #2. We would require a Basic CSF for all potential future minor formulations that will be submitted for this registration.

I am in the office this week, please call me directly if you have any questions.

Thanks!

Terria Northern

**Registration Risk Manager
Environmental Protection Agency
1200 Penn. Ave., NW (7510P)
Washington, DC 20460
#703-347-0265**

**Street address: 2777 Crystal Drive
1 Potomac Yard South
Arlington, VA**

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Monday, November 13, 2017 1:39 PM
To: Bain, Zeno <Bain.Zeno@epa.gov>
Cc: Northern, Terria <Northern.Terria@epa.gov>
Subject: FW: EPA Completed Action 89110-3

Zeno,

I am hoping that you can confirm something for me while Terria is out. I want to make sure that I have understood correctly that in order to address the deficiency in the second bullet point of the attached letter we need to revise the basic and alternate CSF #2 so that the basic becomes Alternate #2 and Alternate #2 becomes the basic. Both formulations will remain on file but we need to change the designation. Is that correct?

Thank you,

**Abigail T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.**

**1150 18th Street NW, Suite 1000
Washington D.C., 20036
United States of America**

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A Science Group Company

I will be out of the office the afternoon of November 17 through Friday, November 24.

From: Northern, Terria [<mailto:Northern.Terria@epa.gov>]

Sent: Monday, November 13, 2017 12:35

To: Abigail Wacek

Cc: Bain, Zeno

Subject: RE: EPA Completed Action 89110-3

Hello Abby – the technical screen failure was sent to you on November 3rd, please respond by Friday, November 17th 2017 or the Agency will proceed with rejecting the submission. I am on leave today but will return, please contact me directly of Zeno Bain.

Thank you.

Terria Northern

Registration Risk Manager
Environmental Protection Agency
1200 Penn. Ave., NW (7510P)
Washington, DC 20460
#703-347-0265

Street address: 2777 Crystal Drive
1 Potomac Yard South
Arlington, VA

From: Northern, Terria

Sent: Friday, November 03, 2017 10:26 AM

To: 'Abigail Wacek' <AWacek@tsgusa.com>

Cc: Bain, Zeno <Bain.Zeno@epa.gov>; OPP AD Ombudsman <OPP_AD_Ombudsman@epa.gov>

Subject: EPA Completed Action 89110-3

Hello Abby – please review the attached technical screen letter and respond within the required timeframe to avoid rejection. I will be out of the office from Nov 6-13, 2017, contact Zeno Bain directly if you have any questions or comments.

Thanks!

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

November 3, 2017

Abigail T.D. Wacek
Isomeric Industries
361 17th Street NW #1224
Atlanta, GA 30363

Subject: Technical Screen Failure
Product Name: Bionix GA 50M
EPA Registration Number: 89110-3
Application Date: August 8, 2017
Decision Number: 532735

Dear Ms. Wacek:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your application has not passed the preliminary technical screening and therefore is subject to rejection if the application is not corrected.

- OCSPP Guideline Number 830.6321, Dielectric Breakdown Voltage Study was not addressed.
- The new proposed formulation for Alt CSF #2 is not considered a 100% repack, the composition has changed from the basic formulation. We are requesting Alt CSF#2 become the Basic CSF, and the current Basic CSF become Alt CSF #2. We would require a Basic CSF for all potential future minor formulations that will be submitted for this registration.

In order for the review of your pesticide product to continue, you will need to correct your application to address the items listed above within 10 business days of the date you received this letter. The EPA recommends sending your correction by email to the contact listed below to ensure it is received in a timely manner. If studies or confidential business information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected. At this time, you could also choose to withdraw your application.

Page 2 of 2
EPA Reg. No. 89110-3
Decision No. 532735

If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be 'Zeno Bain', with a long horizontal stroke extending to the right.

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Northern, Terria

From: ODell, Lindsay
Sent: Thursday, October 26, 2017 11:53 AM
To: Northern, Terria
Cc: Bain, Zeno; Hicks, Karen
Subject: PC Repack tech screen for 89110-3 (Repack)
Attachments: 89110-3.docx

Categories: Red Category, Printing

Hi all:

This is the MUP we had discussed a briefly last week. It is registered as a 100% Repack (Basic CSF) and they are adding Alternate formulation 2 with an unregistered source of the active.

They have addressed all Product chemistry data requirements with the exception of Dielectric breakdown voltage. **We've already discussed that the Alternate formulation 2 be revised to indicate it is the new Basic CSF and the company may list their 100% Repacks as Alternate formulations.** This was primarily based on the fact that the company is now formulating, thus, we would require a Basic CSF for all potential future minor formulations amendments that may be submitted.

Please see the attached PC technical screen form.

Also, Terria scheduled a meeting for this Registration on Monday (10/30).

Lindsay O'Dell

Environmental Protection Specialist
Antimicrobials Division
EPA
703.347.0392

Product Chemistry Checklist for Technical Screens

The Technical Screen for BIONIX GA50M EPA Reg. No./File Symbol 89110-3 DP# 442578

Pass* ☐ Fails ☒

For a complete chemistry review the following are submitted or addressed.

1. Proposed CSF(s) is included in the data package: Yes ☒ No ☐ N/A ☐
2. The signature and date are included on the CSF(s): Yes ☒ No ☐ N/A ☐
3. **Only for A540 or A570 Aerosol disinfectants
 - a. Nominal concentration(s) for active ingredient(s) are correctly calculated:
Yes ☐ No ☐ N/A ☒
 - b. The certified limits for all active ingredients are within 40 CFR standard certified limits: Yes ☐ No ☐ N/A ☒
 - c. Wider certified limits have been requested and rationale has been submitted:
Yes ☐ No ☐ N/A ☒

If any of the below studies are not applicable, a justification from the Registrant must be included.

Group A- Product Identity, Composition, and Analysis Test

OPPTS#	Name	Status
830.1550	Product Identity & Composition	Addressed
830.1600	Description of materials	Addressed
830.1620	Description of production process	Addressed
830.1650	Description of formulation process	Addressed
830.1670	Discussion of formation of impurities	Addressed
830.1700	Preliminary analysis	Addressed
830.1750	Certified limits	Addressed
830.1800	Enforcement analytical method	Addressed
830.1900	Submittal of samples	Addressed

Group B- Physical/Chemical Properties

OPPTS#	Name	Status
830.6302	Color	Addressed
830.6303	Physical state	Addressed
830.6304	Odor	Addressed
830.6313	Stability to normal & elevated temperatures, metals & metal ions	Data Not Required
830.6314	Oxidation/Reduction	Addressed
830.6315	Flammability	Addressed
830.6316	Explosibility	Addressed
830.6317	Storage stability	Addressed
830.6319	Miscibility	Addressed
830.6320	Corrosion characteristics	Addressed
830.6321	Dielectric breakdown voltage	Not Addressed
830.7000	pH	Addressed
830.7050	UV/Visible absorption	Data Not Required
830.7100	Viscosity	Addressed
830.7200	Melting point	Data Not Required
830.7220	Boiling point	Data Not Required
830.7300	Density/relative	Addressed
830.7370	Dissociation constants in water	Data Not Required
830.7520	Particle size	Data Not Required
830.7550/ 7560/ 7570	Partition coefficient	Data Not Required
830.7840/ 7860	Water solubility	Data Not Required
830.7950	Vapor pressure	Data Not Required


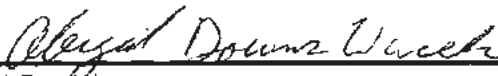
Comments:

The Guideline 830.6321 was not addressed in the MRID 50011202, as cited on the data matrix. This is a data requirement for all end use products, however, the Registrant may choose to submit a waiver request for this guideline.

Passing of the technical screen **does not mean the product chemistry review will be acceptable.*

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number 89110-3		2. EPA Product Manager Zeno Bain	
4. Company/Product (Name) Isomeric Industries / BIONIX GA50M		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name And Address Of Applicant (include ZIP Code) Isomeric Industries 361 17th Street NW #1224 Atlanta, GA 30363		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address			
Section II			
<input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Notification – Explain below. <input type="checkbox"/> Other – Explain Below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) A570 amendment requiring data review to add an unregistered source. A PRIA pre-payment has been made for this action and receipt included in this application (Pay.gov Tracking ID: Pay.gov Tracking ID: 2644KSCF, Agency Tracking ID: 75301106261.)			
Please confirm receipt and forward all communication to Abigail Wacek, Technology Sciences Group, 1150 18th Street, NW, Suite 1000, Washington, D.C. 20036 or awacek@tsqusa.com.			
Section III			
1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container 5 gal pail; 15, 30, 55 gal drum; 275, 330 gal tote bin, bulk tanker	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <u>Self adhesive</u>	
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Abigail Wacek, Technology Sciences Group		Title Regulatory Consultant Telephone No. (Include Area Code) 202-828-8992	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant	
4. Typed Name Abigail T.D. Wacek		5. Date August 8, 2017	

Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000

Washington, D.C. 20036

Direct: (202) 828-8992

Fax: (202) 872-0745

E-Mail: awacek@tsgusa.com

Abigail T. D. Wacek

Regulatory Consultant



August 8, 2017

Zeno Bain, PM 33
Antimicrobials Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: A570 – Amendment Requiring Data Review

Company Name: Isomeric Industries

Product Name: *BIONIX GA50M*

EPA Reg. No.: 89110-3

Dear Mr. Bain,

Technology Sciences Group, Inc., on behalf of Isomeric Industries, hereby submits the enclosed amendment to add an unregistered source to the *BIONIX GA50M* registration. Please find the following enclosed to support this application:

1. Application for Registration (EPA Form 8570-1);
2. Confidential Statement of Formula (EPA Form 8570-4), Alternate #2;
3. Certification with Respect to Citation of Data (EPA Form 8570-34);
4. Data Matrix, confidential and releasable versions (EPA Form 8570-35);
5. Transmittal document and product chemistry data volumes 2 and 3;
6. PRIA category A570, Payment Confirmation Receipt, Pay.gov Tracking ID: 2644KSCF, Agency Tracking ID: 75301105261;
7. Small Business Fee waiver certification letter.

Please do not hesitate to contact me with any questions at (202) 828-8992 or via e-mail: awacek@tsgusa.com.

Sincerely,

Abigail T.D. Wacek
Regulatory Consultant

Washington, D.C.
1150 18th St., NW, Suite 1000
Washington, D.C. 20036
Phone: (202) 223-4392

California
712 Fifth St., Suite A
Davis, CA 95616
Phone: (530) 757-1245

Canada
275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285

August 8, 2017

U.S. Environmental Protection Agency
Document Processing Desk (COADR)
Office of Pesticide Programs
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

RE: ISOMERIC INDUSTRIES INC.
Small Business Waiver – BIONIX GA50M - 89110-3

I, Chris Harken, the President of Isomeric Industries, am authorized and have personal knowledge sufficient to make this certification on behalf of Isomeric Industries. I hereby certify under penalty of perjury that, since Isomeric's waiver request of July 10, 2017, there has been no change in the number of Isomeric's employees, entities affiliated with Isomeric Industries or average gross global revenue from pesticides, including any such revenue from affiliates and that the documentation submitted in connection with the request of July 10, 2017 remains true, complete, and correct and remains valid.

If there are any questions or comments please contact me directly at 678-713-4275

Sincerely,



Chris Harken
President
Isomeric Industries Inc.

**VOLUME 1 OF 3 OF SUBMISSION
TRANSMITTAL DOCUMENT**

NAME AND ADDRESS OF SUBMITTER:

Isomeric Industries
361 17th Street NW #1224
Atlanta, GA 30363

REGULATORY ACTION:

A570 application to add unregistered source to *BIONIX GA50M*, 89110-3.

TRANSMITTAL DATE:

August 8, 2017

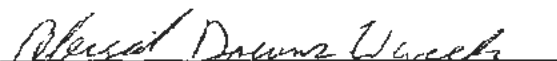
LIST OF SUBMITTED STUDIES:

<u>MRID</u> <u>Number</u>	<u>Volume</u> <u>Number</u>	<u>EPA Study Title</u>	<u>Guideline</u> <u>Number</u>
50011200	1 of 3	Administrative Materials	---
50011201	2 of 3	Product Chemistry of Bionix GA50M - Group A	830.1550 – 830.1900
50011202	3 of 3	Product Properties of Bionix GA50M - Group B	830.6303 – 830.7300

COMPANY NAME:

Isomeric Industries

COMPANY OFFICIAL:


Abigail T.D. Wacek, Regulatory Consultant

COMPANY CONTACT:

Technology Sciences Group
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Phone: 202-828-8992
Email: awacek@tsgusa.com



Receipt

Your payment is complete

Pay.gov Tracking ID: 2644KSCF
Agency Tracking ID: 75301105261
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card
Payment Amount: \$958.00
Transaction Date: 08/08/2017 03:50:43 PM EDT
Payment Date: 08/08/2017
Registration Number: 89110-3
Company Name: Isomeric Industries
Company Number: 89110
Action Code: A570

Account Information

Cardholder Name: Abigail T D Wacek
Card Type: American Express
Card Number: *****1011

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
awacek@tsgusa.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date August 8, 2017	EPA Reg. No./File Symbol 89110-3	Page 1 of 4
Applicant's/Registrant's Name & Address: Isomeric Industries Inc. 361 17th Street NW #1224 Atlanta, GA 30363		Product BIONIX GA50M

Ingredient *Glutaraldehyde (CAS# 111-30-8)*

Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
End Use Product Registration					
830.1550	Product Identity and composition	50011201	Isomeric Industries, Inc.	OWN	
830.1600	Description of materials	50011201	Isomeric Industries, Inc.	OWN	
830.1620	Description of production process	50011201	Isomeric Industries, Inc.	OWN	
830.1650	Description of formulation process	50011201	Isomeric Industries, Inc.	OWN	
830.1670	Discussion of formation of impurities	50011201	Isomeric Industries, Inc.	OWN	
830.1700	Preliminary analysis	50011201	Isomeric Industries, Inc.	OWN	
830.1750	Certified limits	50011201	Isomeric Industries, Inc.	OWN	
830.1800	Enforcement analytical method	50011201	Isomeric Industries, Inc.	OWN	
830.1900	Submittal of samples	50011201	Isomeric Industries, Inc.	OWN	
830.6303	Physical state	50011202	Isomeric Industries, Inc.	OWN	
830.6314	Oxidation / reduction	50011202	Isomeric Industries, Inc.	OWN	
830.6315	Flammability	50011202	Isomeric Industries, Inc.	OWN	
830.6316	Explosibility	50011202	Isomeric Industries, Inc.	OWN	
830.6317	Storage stability	50011202	Isomeric Industries, Inc.	OWN	
830.6319	Miscibility	50011202	Isomeric Industries, Inc.	OWN	
830.6320*	Corrosion characteristics	50011202	Isomeric Industries, Inc.	OWN	
830.6321	Dielectric breakdown voltage	50011202	Isomeric Industries, Inc.	OWN	
830.7000	pH	50011202	Isomeric Industries, Inc.	OWN	
830.7100	Viscosity	50011202	Isomeric Industries, Inc.	OWN	

Signature 	Name and Title Abigail Wacek, Regulatory Consultant	Date August 8, 2017
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WASHINGTON, D.C. 20460

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DATA MATRIX

Date August 8, 2017	EPA Reg. No./File Symbol 89110-3	Page 2 of 4
Applicant's/Registrant's Name & Address: Isomeric Industries Inc. 361 17th Street NW #1224 Atlanta, GA 30363		Product BIONIX GA50M

Ingredient *Glutaraldehyde* (CAS# 111-30-8)

Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density / relative density	50011202	Isomeric Industries, Inc.	OWN	

Data Requirements for Unregistered Source of Glutaraldehyde

870.1100 (81-1)	Acute oral toxicity - rat	00011706 00164370	BASF Corporation	RED	
870.1200 (81-2)	Acute dermal toxicity	44691606	BASF Corporation	RED	
870.1300 (81-3)	Acute Inhalation toxicity - rat	00060275	Petrolite Corporation	RED	
870.2400 (81-4)	Primary eye irritation - rabbit	00117066	BASF Corporation	RED	
870.2500 (81-5)	Primary dermal irritation	00117061	BASF Corporation	RED	
870.2600 (81-6)	Dermal sensitization	43330201	Union Carbide Corporation	RED	
870.2600 (81-8, 82-7, 83-1)	Acute Neurotoxicity	45082401 46250301 44672701	Union Carbide Corporation	OLD	
870.3100 (82-1)	90-Day Oral Toxicity - Rodent	40908101 41089601	Union Carbide Corporation	OLD	
870.3150 (82-1)	90-Day Oral Toxicity - Nonrodent	41480501 46666416	Union Carbide Corporation The Dow Chemical Co.	OLD	
870.6200 (81-8, 82-7, 83-1)	90-Day Neurotoxicity - Rat	164184	Union Carbide Corporation	OLD	
870.4100 (83-1)	Chronic Oral Toxicity - Rodent	46502102	The Dow Chemical Co.	OLD	
870.4200 (83-2)	Carcinogenicity - Two Rodent Species	44672701 46645705	The Dow Chemical Co. Union Carbide Corporation	OLD	
870.3700 (83-3)	Prenatal Developmental toxicity - rat	42154101 42154001	Union Carbide Corporation	OLD	
870.3800 (83-4)	Reproduction and Fertility Effects	46046803	BASF Corporation	OLD	

Signature 	Name and Title Abigail Wacek, Regulatory Consultant	Date August 8, 2017
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date August 8, 2017	EPA Reg. No./File Symbol 89110-3	Page 3 of 4
Applicant's/Registrant's Name & Address: Isomeric Industries Inc. 361 17th Street NW #1224 Atlanta, GA 30363		Product BIONIX GA50M

Ingredient *Glutaraldehyde (CAS# 111-30-8)*

Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100 (84-2)	Reverse mutation assay	112464 112815	Medical Chemical Corp.	OLD	
870.5300/.5375 (84-2)	<i>In vitro</i> mammalian cell assay	164186 92070011	Union Carbide Corporation	OLD	
870.5385/.5395 (84-2)	<i>In vivo</i> Cytogenetics	42707301 44576302	Union Carbide Corporation	OLD	
870.7800 (85-7)	<i>Immunotoxicity</i>	43330201 45472001	Union Carbide Corporation	OLD	
850.2100 (71-1)	Avian oral toxicity	117070 164373 47854	BASF Corporation	RED	
850.1010 (72-2)	Acute Freshwater Invertebrates	117075 125516 42110101	BASF Corporation Union Carbide Corporation	RED	
850.1075	Acute Freshwater Fish	125515 117077 117076 42612102	Union Carbide Corporation BASF Corporation Safe Materials Inc. (SMI)	RED	
850.1075/.1400 (72-1, 72-3)	Fish Early Life Stage	43982401 43649001	Union Carbide Corporation	RED	
850.1300 (72-4)	Aquatic Invertebrate Life-Cycle	43645701 44210801	Union Carbide Corporation	RED	
850.5400	Aquatic Plant Growth (Algal) Tier II	44443101	Union Carbide Corporation	RED	
835.2120 (161-1)	Hydrolysis	42691201 42691701	Union Carbide Corporation	OLD	

Signature

Name and Title

Abigail Wacek, Regulatory Consultant

Date

August 8,
2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date August 8, 2017	EPA Reg. No./File Symbol 89110-3	Page 4 of 4
Applicant's/Registrant's Name & Address: Isomeric Industries Inc. 361 17th Street NW #1224 Atlanta, GA 30363	Product BIONIX GA50M	

Ingredient *Glutaraldehyde* (CAS# 111-30-8)

Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2240 (161-1)	Photodegradation in Water	164375 42462601	BASF Corporation Safe Materials Inc. (SMI)	OLD	
850.6800	Activated Sludge, Respiration Inhibition	46227702	The Dow Chemical Co.	OLD	

Signature

Name and Title

Abigail Wacek, Regulatory Consultant

Date

August 8,
2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 Isomeric Industries, 361 17th Street NW #1224, Atlanta, GA 30363

EPA Registration Number/File Symbol
 89110-3

Active Ingredient(s) and/or representative test compound(s)
 Glutaraldehyde, CAS# 111-30-8

Date
 August 8 2017

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 Industrial microbial control.

Product Name
 BIONIX GA50M

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Abigail Downs Wacek</i>	Date 8/8/17	Typed or Printed Name and Title Abigail T.D. Wacek, Regulatory Consultant
---	----------------	--



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 31, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-532735
EPA File Symbol or Registration Number: 89110-3
Product Name: BIONIX GA50M
EPA Receipt Date: 29-Aug-2017
EPA Company Number: 89110
Company Name: ISOMERIC INDUSTRIES

MS. ABIGAIL T.D. WACEK
RR CONSULTING SERVICES, INC.
ISOMERIC INDUSTRIES
1150 18th STREET, NW, SUITE 1000
WASHINGTON, D.C. 20036

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

A handwritten signature in black ink, appearing to be "CW" or similar, written over a horizontal line.

Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 05, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

TECHNOLOGY SCIENCES GROUP, INC.
ISOMERIC INDUSTRIES
1150 18TH STREET, NW., SUITE 1000
WASHINGTON, DC 20036

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 29-AUG-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

**VOLUME 1 OF 3 OF SUBMISSION
TRANSMITTAL DOCUMENT**

NAME AND ADDRESS OF SUBMITTER:

Isomeric Industries
361 17th Street NW #1224
Atlanta, GA 30363

REGULATORY ACTION:

A570 application to add unregistered source to *BIONIX GA50M*, 89110-3.

TRANSMITTAL DATE:

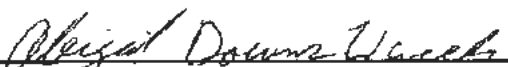
August 8, 2017

LIST OF SUBMITTED STUDIES:

<u>MRID Number</u>	<u>Volume Number</u>	<u>EPA Study Title</u>	<u>Guideline Number</u>
50011200	1 of 3	Administrative Materials	---
50011201	2 of 3	Product Chemistry of Bionix GA50M - Group A	830.1550 – 830.1900
50011202	3 of 3	Product Properties of Bionix GA50M - Group B	830.6303 – 830.7300

COMPANY NAME: Isomeric Industries

COMPANY OFFICIAL:


Abigail T.D. Wacek, Regulatory Consultant

COMPANY CONTACT:

Technology Sciences Group
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Phone: 202-828-8992
Email: awacek@tsgusa.com

Technology Sciences Group Inc.
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036
Direct: (202) 828-8992
Fax: (202) 872-0745
E-Mail: awacek@tsgusa.com
Abigail T. D. Wacek
Regulatory Consultant



August 8, 2017

Zeno Bain, PM 33
Antimicrobials Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room 5-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: A570 – Amendment Requiring Data Review
Company Name: Isomeric Industries
Product Name: *BIONIX GA50M*
EPA Reg. No.: 89110-3

Dear Mr. Bain,

Technology Sciences Group, Inc., on behalf of Isomeric Industries, hereby submits the enclosed amendment to add an unregistered source to the *BIONIX GA50M* registration. Please find the following enclosed to support this application:

1. Application for Registration (EPA Form 8570-1);
2. Confidential Statement of Formula (EPA Form 8570-4), Alternate #2;
3. Certification with Respect to Citation of Data (EPA Form 8570-34);
4. Data Matrix, confidential and releasable versions (EPA Form 8570-35);
5. Transmittal document and product chemistry data volumes 2 and 3;
6. PRIA category A570, Payment Confirmation Receipt, Pay.gov Tracking ID: 2644KSCF, Agency Tracking ID: 75301105261;
7. Small Business Fee waiver certification letter.

Please do not hesitate to contact me with any questions at (202) 828-8992 or via e-mail: awacek@tsgusa.com.

Sincerely,

Abigail T.D. Wacek
Regulatory Consultant

Washington, D.C.
1150 18th St., NW, Suite 1000
Washington, D.C. 20036
Phone: (202) 223-4392

California
712 Fifth St., Suite A
Davis, CA 95616
Phone: (530) 757-1245

Canada
275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285



U.S. Environmental Protection Agency
Document Processing Desk (COADR)
Office of Pesticide Programs
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

August 8, 2017

RE: ISOMERIC INDUSTRIES INC.
Small Business Waiver – BIONIX GA50M - 89110-3

I, Chris Harken, the President of Isomeric Industries, am authorized and have personal knowledge sufficient to make this certification on behalf of Isomeric Industries. I hereby certify under penalty of perjury that, since Isomeric's waiver request of July 10, 2017, there has been no change in the number of Isomeric's employees, entities affiliated with Isomeric Industries or average gross global revenue from pesticides, including any such revenue from affiliates and that the documentation submitted in connection with the request of July 10, 2017 remains true, complete, and correct and remains valid.

If there are any questions or comments please contact me directly at 678-713-4275

Sincerely,

A handwritten signature in black ink, appearing to read "CH HARKEN", written over a horizontal line.

Chris Harken
President
Isomeric Industries Inc.



Receipt

Your payment is complete

Pay.gov Tracking ID: 2644KSCF
Agency Tracking ID: 75301105261
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card
Payment Amount: \$958.00
Transaction Date: 08/08/2017 03:50:43 PM EDT
Payment Date: 08/08/2017
Registration Number: 89110-3
Company Name: Isomeric Industries
Company Number: 89110
Action Code: A570

Account Information

Cardholder Name: Abigail T D Wacek
Card Type: American Express
Card Number: *****1011

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
awacek@tsgusa.com

PROCESSING REQUEST

Reg # 89110-3

Decision # 521473

Description: New product

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 11/29/16

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket)

☒ New CSF(s) Dated:

BASIC 9/13/16

AU1 10/14/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: A. Heffernan

Division: AD

Phone: 347-8602

Date: 11/29/16



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:

89110-3

Date of Issuance:

11/29/16

Term of Issuance:

Conditional

Name of Pesticide Product:

Bionix GA50M

Name and Address of Registrant (include ZIP Code):

Isomeric Industries
361 17th Street NY #1224
Atlanta, GA 30363

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33
Regulatory Management Branch I, Antimicrobials Division (7510P)

Date:

11/29/16

2. You are required to comply with the data requirements described in the DCI identified below:

a. Glutaraldehyde GDCI-043901-30859

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>.

3. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 89110-3."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated September 13, 2016
- Alternate CSF 1 dated October 14, 2016

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,



Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Accepted Label

BIONIX GA50M

FOR MANUFACTURING USE ONLY. FOR FORMULATING INDUSTRIAL BACTERICIDES AND PRESERVATIVES. FORMULATORS USING THIS PRODUCT ARE RESPONSIBLE FOR PROVIDING DATA FOR THE EPA REGISTRATION OF THEIR FORMULATED PRODUCTS.

Active Ingredient:

Glutaraldehyde:..... 50.0%

Other Ingredients: 50.0%

Total: 100.0%

EPA Reg. No. 89110-TBD EPA Est. **NET CONTENTS:** As Marked on Container

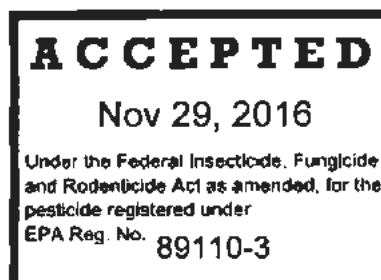
**KEEP OUT OF REACH OF CHILDREN
DANGER**

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to physician: Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.	

[See side panels for additional Precautionary Statements]

In case of emergency, call INFOTRAC: (800)-535-5053

Manufactured for:
ISOMERIC INDUSTRIES
361 17TH Street NW #1224
Atlanta, GA 30363
678-665-4275



Bionix GA50M (89110-TBD)

Isomeric Industries

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PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Causes skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper-reactive individuals. Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Wear goggles, protective clothing, and butyl or nitrile gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

User Safety Recommendations

BEFORE HANDLING OR USING THIS PRODUCT, SEE YOUR EMPLOYER AND READ THE CURRENT SAFETY DATA SHEET. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must wash hands before eating, drinking, chewing gum, or using the toilet. Users must remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans, or public water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FOR FORMULATION OF INDUSTRIAL BACTERICIDES AND PRESERVATIVES FOR USE IN:

- AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS, RECIRCULATING COOLING AND PROCESS WATER SYSTEMS INCLUDING THOSE THAT CONTAIN REVERSE OSMOSIS MEMBRANES, SERVICE WATER AND AUXILIARY SYSTEMS, HEAT TRANSFER SYSTEMS, WASTEWATER SYSTEMS INCLUDING WASTEWATER SLUDGE AND HOLDING TANKS.
- BEET SUGAR MILLS AND BEET SUGAR MILL PROCESS WATER SYSTEMS.
- PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS, PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD, WATER BASED COATINGS FOR PAPER AND PAPERBOARD
- WATER BASED CONVEYOR LUBRICANTS AND AQUEOUS METALWORKING FLUIDS AND IN INDUSTRIAL, INSTITUTIONAL AND CONSUMER PROCESSES AND PRODUCTS IN AQUEOUS-BASED SOLUTIONS, SLURRIES AND EMULSIONS.
- OIL WELL DRILLING, OIL FIELD PROCESSING APPLICATIONS, OIL FIELD WATER SYSTEMS, GAS PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS AND GAS STORAGE FIELDS AND EQUIPMENT SUCH AS STEAM INJECTION WATER HOLDING TANKS, FLOOD WATER, INJECTION WATER, HOLDING POND WATER, DISPOSAL-WELL WATER, WATER HOLDING TANKS, FUEL STORAGE TANKS AND RELATED REFINERY AND OIL FIELD CLOSED, INDUSTRIAL RECIRCULATING WATER HANDLING SYSTEMS.

Bionix GA50M (89110-TBD)

Isomeric Industries

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- NON-FOOD CONTACT SURFACES OF ANIMAL PRODUCTION FACILITIES AND FARM EQUIPMENT SUCH AS: POULTRY & TURKEY HOUSES, SWINE HOUSING AND FARROWING AREAS, BARNs AND LARGE ANIMAL BUILDINGS, HATCHERS, SETTERS AND CHICK PROCESSING FACILITIES, CAGES AND TRANSPORT VEHICLES, AND FOR SANITIZING INDUSTRIAL OR NON-FOOD CONTACT SURFACES SUCH AS EQUIPMENT FOR MIXING, PACKING, OR PACKAGING PRODUCTS, PRODUCT TRANSFER LINES, STORAGE TANKS, FLOORS, AND WALLS.
- USES NOT REGISTERED IN THE STATE OF CALIFORNIA: OIL PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS, FRACTURING FLUIDS.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE

This product is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. The product can be stored and handled in baked phenolic -lined steel, polyethylene, stainless steel, or reinforced epoxy -plastic equipment. This product freezes at about -6°F (-21°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8° C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C).

Handle in a well -ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

PESTICIDE DISPOSAL

Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Triple or pressure rinse container (or equivalent) promptly after emptying.

(For containers 5 gallons or less)

Triple Rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

(For containers larger than 5 gallons)

Clean container promptly after emptying. Triple Rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or other procedures approved by state and local authorities

Bionix GA50M (89110-TBD)

Isomeric Industries

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WARRANTIES AND WARRANTY DISCLAIMERS

Conditions of Sale: Isomeric Industries ("ISOMERIC") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to ISOMERIC. To the extent consistent with applicable law, ISOMERIC DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. To the extent consistent with applicable law, ISOMERIC SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL, OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, and ISOMERIC's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price. BUYER AND USER ACKNOWLEDGE AND ASSUME ALL RISKS AND LIABILITY RESULTING FROM HANDLING, STORAGE AND USE OF THIS PRODUCT. ISOMERIC DOES NOT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE ANY OTHER WARRANTY, GUARANTEE OR REPRESENTATION CONCERNING THIS PRODUCT.

Bionix GA50M (89110-TBD)

Isomeric Industries

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Page 4 of 4

Heffernan, Aline

From: Abigail Wacek <AWacek@tsgusa.com>
Sent: Thursday, November 03, 2016 7:56 PM
To: Heffernan, Aline
Subject: RE: 89110-G 100% Repack
Attachments: 89110-TBD.201609134.Bionix GA50M Clean.pdf; 89110-TBD.201609134.Bionix GA50M Redline.pdf

Aline,

Please see the revised label attached.

Thank you!

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
Visit us at www.TSGUSA.com

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From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Tuesday, November 01, 2016 10:10
To: Abigail Wacek
Subject: RE: 89110-G 100% Repack

Abby,

I was looking over your label and the proposed changes look ok to me. One of the changes I mentioned earlier was adding not for food contact surfaces to the Animal Production Facilities directions. [REDACTED] the directions clearly state not for food contact. Please revise the label to include this change.

Thank you,

Aline

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Tuesday, November 01, 2016 9:22 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: 89110-G 100% Repack

Aline,

Per our call we have removed "functional fluids" and clarified "water based conveyor lubricants" on page two of the label. Please see the redline and clean copies of the label attached. Please let me know if any additional changes are required at this time.

Thank you!

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
Visit us at www.TSGUSA.com

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From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Friday, October 28, 2016 15:17
To: Abigail Wacek
Subject: RE: 89110-G 100% Repack

Abby,

Were you able to get into contact with your client about the requested changes to the label?

Aline

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Wednesday, October 19, 2016 9:49 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: 89110-G 100% Repack

Aline,

Let me speak with my client to get clarification on that use site. I will also tell them about the label revision. I do not anticipate that they will have any questions about that change.

Thanks,

Abby

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
Visit us at www.TSGUSA.com

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From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Tuesday, October 18, 2016 15:52
To: Abigail Wacek
Subject: RE: 89110-G 100% Repack

Abby,

I looked over the label you sent and I have a few additional questions. It is unclear to me how functional fluids and lubricants are the same as aqueous metalworking fluids.

In the direction for animal production facilities and farm equipment could you add clearly non-food contact surfaces only or something to that effect. [REDACTED], this use clearly says for non-food contact surfaces. To prevent any confusion it would be beneficial to have this statement on the label.

Thank you,

Aline

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Friday, October 14, 2016 11:10 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: 89110-G 100% Repack

Aline,

Thank you for the call today. Per our call today please see the attached revised CSF with [REDACTED] removed as an alternate supplier. This product was inadvertently included in the CSF but is not an MUP and so therefore not applicable to this formulation. I apologize for the error. Please also find the attached revised product label, clean and redline copies.

Per our discussion today I believe that the primary use sites of concern were the hatching eggs, function fluids and lubricants, and the oil well uses. Isomeric has removed the hatch eggs use site, see attached. The functional fluids and lubricants are a part of the larger aqueous metal working fluids and industrial processes and water systems, a use site which is found on both the BASF and Dow label with slightly more generic names. Lastly, the draft Isomeric label states oil well drilling, oil field processing applications, and oil field water systems. The Dow label qualifies these uses under the general term "Oil and Gas Production applications" and the BASF label under the general term "oil field applications including drilling muds, workover, fracturing, completion and packer fluids."

While the terminology is slightly different we believe that these use sites all fall under the same category. This is supported by the Industrial Processes and Water Systems use site in the RED which includes the following uses: oil-storage tanks; waterfloods; drilling muds, drilling, completion, and workover fluids; packer fluids; gas-production and transmission pipe systems; gas storage wells and systems; hydrotesting; pipeline pigging and scraping operations; paper mills and paper mill process water systems; pigments, filler slurries and water based coatings for paper and paperboard; metalworking fluids; water-based conveyor lubricants; air washer and industrial scrubbing; systems/recirculating cooling and process water systems; service water and auxiliary systems; heat transfer systems; industrial waste-water systems; and sugar beet mills and process water systems.

I hope that this has addressed your concerns. Please let me know if you have any questions or if any additional changes are needed. Thank you again for your call today.

Have a nice weekend!

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
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From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Friday, September 30, 2016 11:33
To: Abigail Wacek
Subject: 89110-G 100% Repack

Ms. Wacek,

I am working on your PRIA for 89110-G. Please refer to the guidance for a 100% repack. The new product's label may include **only** those use sites approved on the labels of **all** products being repackaged. Please revise the label and/or the CSFs and resubmit.

Thank you,

Aline Heffernan
Regulatory Management Branch 1
Antimicrobials Division
Office of Pesticide Programs
703-347-8602

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PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 9/14/16Experts In-Processing Signature: MP Date 9/14/16 Fee Paid: Yes Division management contacted on issues No Yes Date

EPA Reg. Number: <u>89110-G</u>		EPA Receipt Date: <u>9/14/16</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>No There to Review 100% Re-Pack</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					X
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5					X
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			
<p>Comments:</p> <p>* Documentation: (Pass / Fail)</p> <p>- Request forms are complete</p> <p>* Zuercher: (Pass / Fail)</p> <p>- no Zuercher to review</p> <p>- low Y. Re-Pass</p> <p>* PKN 11-3: (Pass / Fail)</p> <p>- no studies submitted</p> <p>JL 9-27-16 * Overall Status (Pass / Fail)</p>				

Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000

Washington, D.C. 20036

Direct: (202) 828-8992

Fax: (202) 872-0745

E-Mail: awacek@tsgusa.com

Abigail T. D. Wacek

Regulatory Consultant



September 13, 2016

Julie Chao

Antimicrobials Division (7504P)

Office of Pesticide Products

U.S. Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

Submitted electronically

Re: A530-Application for a New Product: 100% Re-Package

Company Name: Isomeric Industries

Product Name: BIONIX GA50M

EPA Reg. No.: 89110-TBD

Dear Julie,

Technology Sciences Group, Inc., on behalf of Isomeric Industries, hereby submits the enclosed application to register *BIONIX GA50M*. This product is a 100% re-package of several identical 50% glutaraldehyde Manufacturing Use Product (MUP) registrations. Please find the following enclosed to support this application:

1. Application for Registration (EPA Form 8570-1);
2. Confidential Statement of Formula (EPA Form 8570-4) Basic and Alternate #1;
3. Formulator's Exemption (EPA Form 8570-27);
4. Product Label dated September 13, 2016;
5. PRIA category A530, Payment Confirmation Receipt, Pay.gov Tracking ID: 25TQK42V, Agency Tracking ID: 75089348174;
6. Small Business Waiver certification statement;
7. Letter of Authorization.

Please do not hesitate to contact me with any questions at (202) 828-8992 or via e-mail:

awacek@tsgusa.com.

Sincerely,

Abigail T.D. Wacek
Regulatory Consultant

Washington, D.C.
1150 18th St., NW, Suite 1000
Washington, D.C. 20036
Phone: (202) 229-4392

California
712 Fifth St., Suite A
Davis, CA 95616
Phone: (530) 757-1245

Canada
275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285

Abigail Wacek

From: notification@pay.gov
Sent: Saturday, September 10, 2016 16:29
To: Abigail Wacek
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25TQK42V
Agency Tracking ID: 75089348174
Transaction Type: Sale
Transaction Date: 09/10/2016 04:28:41 PM EDT

Account Holder Name: Chris A Harken

Transaction Amount: \$320.00
Card Type: AmericanExpress
Card Number: *****2005

Registration Number: 89110-TBD
Company Name: ISOMERIC INDUSTRIES INC.
Company Number: 89110
Action Code: A530

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

1
DO NOT REPLY

Form approved. OMB No. 2070-0080, 2070-0057, 2070-0107, 2070-0122, 2070-0164.



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Isomeric Industries 361 17th Street NW #1224 Atlanta, GA 30363	EPA File Symbol/Registration Number 89110-TBD
	Product Name BIONIX GA50M
	Date of Confidential Statement of Formula (EPA Form 8570-4) 09/13/2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Glutaraldehyde (43901)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Glutaraldehyde (43901)		
Signature <i>Abigail D. Wacek</i>	Name and Title Abigail T. D. Wacek, Consultant	Date 09/13/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

		United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I					
1. Company/Product Number 89110-TBD		2. EPA Product Manager Julie Chao		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Isomeric Industries / BIONIX GA50M		PM# 33			
5. Name And Address Of Applicant (Include ZIP Code) Isomeric Industries 361 17th Street NW #1224 Atlanta, GA 30363		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
<input type="checkbox"/> Check if this is a new address					
Section II					
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Notification – Explain below. <input type="checkbox"/> Other – Explain Below.					
Explanation: Use additional page(s) if necessary. (For section I and Section II.) A530 100% re-pack application for a new manufacturing use product. A PRIA pre-payment has been made for this action and receipt included in this application (Pay.gov Tracking ID: Pay.gov Tracking ID: 25TQK42V, Agency Tracking ID: 75089348174.) Please confirm receipt and forward all communication to Abigail Wacek, Technology Sciences Group, 1150 18th Street, NW, Suite 1000, Washington, D.C. 20036 or awacek@tsqusa.com.					
Section III					
1. Material This Product Will Be Packaged In:					
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container 5 gal pail; 15, 30, 55 gal drum; 275, 330 gal tote bin, bulk tanker		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label Is Affixed to Product		<input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <u>Self adhesive</u>			
Section IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Abigail Wacek, Technology Sciences Group		Title Regulatory Consultant		Telephone No. (Include Area Code) 202-828-8992	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Abigail T.D. Wacek		5. Date September 13, 2016			

Title

Product Chemistry of *Bionix GA50M* - Group A Amended

Data Requirements

OCSPP Guidelines 830.1620

Description of Production Process

Authors

Luminita M. Velea, Ph.D.

Study Completed on

December 26, 2017

Study Sponsor

Isomeric Industries Inc.
361 17th Street NW #1224
Atlanta, GA 30363

Performing Laboratory

N/A

Prepared by

Technology Sciences Group Inc.
1150 18th St. N.W., Suite 1000
Washington, D.C. 20036

Pages 103-108 - *Confidential Statements of Formula may be entitled to confidential treatment*